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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/493,480	01/28/2000	Martin A. Cheever	0140580-009810	2303

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EXAMINER

HOLLERAN, ANNE L

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 03/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/493,480	<b>Applicant(s)</b> CHEEVER ET AL.	
	<b>Examiner</b> Anne Holleran	<b>Art Unit</b> 1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 28 December 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 93,97-103 and 107-130 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 93, 97-103, 107-130 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/28/2004 has been entered.

2. The amendment filed December 28, 2004 is acknowledged.

Claims 93, 97-103, 107-130 are pending and examined on the merits.

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### ***Claim Rejections Withdrawn:***

3. The rejection of claims 93, 97-103, 107-116, 121 and 124-130 under 35 U.S.C. 112, first paragraph, as containing subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention is withdrawn in view of the amendment clarifying that the immune response is to a Her-2/Neu protein and upon further

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consideration of the teachings of the specification with regard to the recitation of “at least 90% identical to an amino acid sequence...”.

4. The rejection of claims 93, 97-103, 107-112, 117, 118 and 122 under 35 U.S.C. 102(e) as being anticipated by Kipps (U.S. Patent 6,287,569; issued Sep. 11, 2001; effective filing date Apr. 10, 1997) is withdrawn in view of the amendment.

5. The rejection of claims 93, 99-101, 103, 109-111, and 125-129 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kipps (supra) in view of Carrano (U.S. Patent 5,962,428; issued Oct. 5, 1999; effective filing date Sep. 16, 1996) is withdrawn in view of the amendment.

6. The rejection of claims 93, 99-101, 103, 109-111, and 130 under 35 U.S.C. 103(a) as being unpatentable over Kipps (supra) in view of Krieg (U.S. Patent 6,429,199; issued Aug. 6, 2002; filing date Nov. 13, 1998) is withdrawn in view of the amendment.

***Claim Rejections Maintained and New Grounds of Rejection:***

7. Claims 93, 97-103, 107-130 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 36 are indefinite because the recitation “a non-Her-2/Neu sequence” is unclear. The specification contains no definition of this phrase. The phrase is used in the

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context of defining a linking group between an extracellular domain and a phosphorylation domain of a Her-2/Neu. Does non-Her-2/Neu sequence, which is assumed to be a sequence as small as a dipeptide, mean that the sequence may not appear in any part of any Her-2/Neu amino acid sequence? Or is this recitation limited to sequences of domains (for example, a non-Her-2/Neu sequence is a sequence that is not an extracellular domain, a transmembrane domain or a phosphorylation domain of any Her-2/Neu sequence)?

8. Claims 93, 97-103, 107-118, 121, 122, 124-130 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Claims 93, 97-103, 107-118, 121, 122, 124-130 are drawn to isolated nucleic acids encoding a polypeptide comprising ECD-PD(extracellular domain-phosphorylation domain) fusion proteins where the ECD of Her-2/Neu is linked to a PD of Her-/Neu by a linker that consists of a "non-Her-2/Neu sequence". Applicants point to support for this sequence on page 31, lines 29-31. This passage does not appear to provide support for the broad concept of a "non-Her-2/Neu sequence" because the passage pointed to appears to teach specific types of linkers that are known in the art. Therefore, the passage pointed to merely points to examples of linkers that might fall within the scope of a "non-Her-2/Neu sequence". Specific examples are not commensurate in scope with the scope of the broad term of "non-Her-2/Neu sequence". Therefore, the use of the broader term appears to be a change in scope from what was originally

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contemplated at filing. Therefore, one of skill in the art would not find that applicants were in possession of the claimed fusion proteins that comprise linkers that are “non-Her-2/Neu sequence[s]”.

9. The rejection of claims 93-97, 102, 103, 107, 112, 113, 117, and 118 under 35 U.S.C. 102(e) as being anticipated by Hudziak (U.S. Patent 6,015,567; issued Jan. 18, 2000; effective filing date May 19, 1989; cited in the IDS) is maintained.

Applicant argues that the claimed polypeptides are not anticipated by Hudziak because Hudziak's protein contains a few amino acids of the transmembrane domain, and that having a few amino acids from the transmembrane domain constitutes a linker that is a Her-2/Neu sequence. However, the term “non-Her-2/Neu sequence” is not definite and appears to introduce new matter into the specification. Because the term “non-Her-2/Neu sequence” is indefinite, it is possible to interpret the phrase “non-Her-2/Neu sequence” as a sequence that does not consist of a Her-2/Neu domain. A sequence of a few amino acids derived from the transmembrane region is not the same as a sequence of a Her-2/Neu transmembrane domain. Therefore, the rejection is maintained for the reasons of record.

### ***Conclusion***

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the Office should be directed to Anne Holleran, Ph.D. whose telephone number is (571) 272-0833. Examiner Holleran can normally be reached Monday through Friday, 9:00 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew, can be reached at (571) 272-0787.

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Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist at telephone number (703) 571-1600.

Anne L. Holleran

Patent Examiner

March 21, 2005



HOLLERAN, PH.D.

PRIMARY EXAMINER